UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/429,832	10/29/99	BHAT R	0646/1D205-U

025291 HM12/0522
AMERICAN HOME PRODUCTS CORPORATION
PATENT SECTION
FIVE GIRALDA FARMS
MADISON NJ 07940-0874

EXAMINER	
BASI,N	
ART UNIT	**PAPER NUMBER**
1646	8

DATE MAILED: 05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/429,832	Bhat et al
Examiner	**Art Unit**
Nirmal. S. Basi	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 12, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *17-27* is/are pending in the application.

4a) Of the above, claim(s) *19-27* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *17 and 18* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *17-27* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2 and 6*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. The Response to Restriction Requirement filed 3/12/00 has been entered.

2. Applicant's election with traverse of claims 17-18 (Group I) in Paper No. 7 (Filed 3/12/01) is acknowledged. The traversal is on the ground(s) that "claims of Group IV, 19-12, should be considered together with the claims of Group I. Applicant argues, "These groups of claims are related, as the Examiner noted, as product and process of use", "Using the novel products of Group I in any process requires determining the novelty of the products of Group 1". Applicants arguments have been fully considered but not found persuasive. Claims 17 and 18 are directed to a product that is not allowable (see action, below). Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 19-22, and newly added claims 24-27, directed to the process of making or using the product, withdrawn from consideration as a result of a restriction requirement, will not be rejoined at this time. This request to rejoin claims 19-22 and 24-27, directed to the process of making or using the product, in light of In re Ochiai, must be submitted upon the indication of the allowability of the product claims. Claims 19-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

3. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title

37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Sequences in Figure 1 must be identified by their corresponding SEQ ID NO:. Also the specification contains sequences without the assigned identifier. Compliance with sequence rules is required.

4. ***Claim Rejection, 35 U.S.C. 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite because it is not clear what is a "function conservative variant". "Function conservative variant" has not been defined in the specification nor claims so as to allow the metes and bounds of the claim to be determined. Further the claim is indefinite because the term "variant" carries no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated polypeptides. Also, it is not clear what "function" is being claimed and what structure the recited "function-conservative variants" possess so as to allow the metes and bounds the claim to be determined.

Claims 18 is indefinite for depending on an indefinite base claim and fails to resolve the issues raised above.

5. Claims 17 and 18 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to purified polypeptide:

a) comprising function-conservative variants of the polypeptide of SEQ ID NO:2

b) comprising amino acids 1-45 of the sequence depicted in SEQ ID NO:2.

The specification discloses an isolated cDNA sequence, SEQ ID NO: 1 which encodes the polypeptide depicted in SEQ ID NO:2. The instant disclosure of a single distinct polypeptide does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, mutated, variant and fusion proteins. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by an amino acid sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly &*

Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information on the "function-conservative variants" and peptide comprising amino acids 1-45, such as definitive structural features of the claimed genus of polypeptides and the claim fails to disclose the functional features of the claimed genus of polypeptides. The common function of "function-conservative variants" and peptide comprising amino acids 1-45, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. The specification proposes to isolate "function-conservative variants" from wild type, mutant cells, heterologous organisms (page 20) and produce said variants by replacement of amino acids (page 15). There is no description, however, of the sites at which variability may be tolerated, which amino acids are to be substituted to produce "function-conservative variants" and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to make, isolate , identify and use the claimed "function-conservative variants" and polypeptide comprising amino acids 1-45 of SEQ ID NO:2 encompassed without undue experimentation.

An adequate written description of a protein, requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of a protein is more than

a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the protein itself. Accordingly, the specification does not provide a written description of the invention of claim 17.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 17 is are rejected under 35 U.S.C. 102(a) as being anticipated by Karo Bio AB (See IDS ref. WO 97/09348).

Karo Bio AB disclose two estrogen receptors (claim 1, Fig 13A and 14A), the first of which has 91.1% query match and 99.8% best local similarity to SEQ ID NO:2 of instant application , and the second of which has 81.7% query match and 88.7% best local similarity to SEQ ID NO:2 of instant application, (see attached succinic comparison). The receptors disclosed by Karo Bio AB are inherently function-conservative variants of the polypeptide of SEQ ID NO:2, absent evidence to the contrary. Therefore, the teachings of Karo Bio AB, anticipate claim 17 by disclosing a function-conservative variant of the polypeptide of SEQ ID NO:2.

Claim 17 is are rejected under 35 U.S.C. 102(a) as being anticipated by Mosselman et al (See IDS ref. FEBS letters, 392, pages 49-53, 1996).

Mosselman discloses an estrogen receptor (ERβ) which comprises a fragment having identical amino acid sequence to residues 50-526 of SEQ ID NO:2 of instant application. The ERβ of Mosselman is activated 17 β-estradiol and is inherently a function-conservative variant of the polypeptide of SEQ ID NO:2, absent evidence to the contrary. Therefore, the teachings of Mosselman, anticipate claim 17 by disclosing a function-conservative variant of the polypeptide of SEQ ID NO:2.

No claim is allowed.

Advisory Information

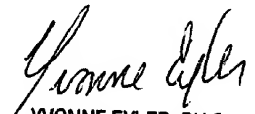
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
May 17, 2001



YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600